JAN 26 1999

K983809

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):	Regulatory & Marketing Services, Inc. (RMS) 3234 Ella Lane New Port Richey, FL 34655 Phone: 813-376-4154 Fax: 813-376-7186
Contact Person:	Ed Ransom or Pat Lamb
Date of Summary:	October 28,1998
Trade Name:	KLS-Martin Intraoral Zurich Ramus Distractor
Classification Name:	Ridgid External Distractor
Predicate Device:	KLS-Martin Intraoral Horizontal Distractor
Device Description Comparison:	**The KLS-Martin distractor device is designed to distract the mandible in cases of deficiency or posttraumatic effects of the mandible.**
Intended Use:	**An uni-directional, intra oral device for the distraction of the ascending ramus and mandibular body.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2001

KLS-Martin L.P.
C/O Mr. Arthur J. Ward
Regulatory & Marketing Services, Incorporated (RMS)
3234 Ella Lane
New Port Richey, Florida 34655

Re: K983809
Trade Name: KLS Martin Intraoral Zurich Ramus Distractor
Regulatory Class: II
Product Code: MQN
Dated: December 8, 2000
Received: December 12, 2000

Dear Mr. Ransom:

This letter corrects our substantially equivalent letter of December 8, 2000 regarding the Trade Name.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your

premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note that the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown

Device Name: Intra-oral Mandibular Distractor

Indications For Use:

An uni-directional, intra-oral device for the distraction of the ascending ramus and mandibular body.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983809

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)